In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

DANIELLE DOTSON, as parent and natural guardian of B.M., a minor,	*	No. 17-637V
Petitioner,	*	Special Master Christian J. Moran
v.	*	
	*	Filed: January 10, 2025
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner;
Naseem Kourosh, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING ENTITLEMENT[1]

Danielle Dotson alleges a ProQuad vaccine (specifically the varicella portion) harmed her son, B.M. The basic chronology is that B.M. was vaccinated and approximately three weeks later, developed a severe neurologic problem for with he was hospitalized for about two weeks.

While he was being treated, the doctors did not reach a consensus about the condition afflicting him. Possibilities included either vasculitis in his central

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

nervous system or an encephalitis potentially due to an infection with a strain of the coronavirus. Unfortunately, the illness has impaired B.M.'s development.

In this litigation, Ms. Dotson has retained three experts to support her claim. They are M. Eric Gershwin, a rheumatologist with additional training in immunology; David Wilson, a radiologist; and Yuval Shafrir, a pediatric neurologist. Together, they opined that B.M. suffered from vasculitis and the varicella vaccine caused the vasculitis.

The Secretary opposes an award of compensation. He has retained two experts, Michael Kruer (a pediatric neurologist) and William Zucconi (a radiologist). Collectively, they opine that viral encephalitis, not vasculitis, is the appropriate diagnosis for B.M. They also maintain that the varicella vaccine did not harm B.M. After the experts disclosed their opinions, the parties advocated through two rounds of briefing.

A review of this material leads to the conclusion that Ms. Dotson is not entitled to compensation. The complicated question of whether B.M. suffered from vasculitis as opposed to encephalitis need not be resolved. Even if Ms. Dotson had established with preponderant evidence that B.M. suffered from vasculitis as her experts assert, Ms. Dotson has not met her burden of establishing that the varicella vaccine caused B.M.'s vasculitis.

I. Facts

A. Early Medical History

B.M. was born in August 2013. Exhibit 6 at 16. He periodically saw his pediatrician during his first five years of life. Exhibit 2 at 36-55.

B.M. had a well-child visit on November 7, 2014. Exhibit 2 at 31. His development was normal. Id. at 31-35. B.M. received a dose of the allegedly causal ProQuad vaccine.[2]

Twenty-four days later, B.M. returned to his pediatrician due to a fever, which had started the day before. Exhibit 2 at 27 (Dec 2, 2014). His mother

[2] The ProQuad vaccine contains attenuated, but live, measles, mumps, rubella, and varicella viruses. Riley v. Sec'y of Health & Hum. Servs., No. 15-104V, 2021 WL 4592821, at *12 (Fed. Cl. Spec. Mstr. Aug. 31, 2018). B.M. also received doses of the hepatitis A, influenza, and pneumococcal vaccines. However, his claim rests upon the varicella component of the ProQuad vaccine. Am. Pet., filed Nov. 7, 2014.

reported that the previous night, his temperature had reached 103.2°. On examination, his temperature was 101.6°. Id. The examination also revealed that B.M. was lethargic and not responsive. An examination of his ears revealed erythematosus in his left eardrum. The pediatrician diagnosed him as suffering from fever, seizures, and otitis media. Id. at 27-29. Dr. Kruer opined that B.M.'s initial presentation of a fever and otitis media was consistent with B.M. having a viral infection. Exhibit C at 2. Because the pediatrician was concerned about seizures, B.M. was sent to the emergency room at Norton's Children's Hospital in Louisville, Kentucky.

B. **Norton's Children's Hospital**[3]

B.M. stayed for approximately two weeks. During this time, as the doctors ran various tests and prescribed treatments, their assessments of what was affecting B.M. changed. While an overview of his treatment can be found in the discharge report (Exhibit 3 at 6-35), the most relevant records are summarized on a roughly day-to-day basis.

1. December 2, 2014

B.M. was actively seizing when he arrived at the emergency department. Exhibit 3 at 313-16. For the seizures, doctors gave him Ativan (lorazepam), Keppra (levetiracetam), and fosphenytoin. Id. at 6, 314-16.

B.M.'s mother also reported that he had a one-day history of fever, decreased activity, and decreased responsiveness. The doctors prescribed Rocephin (ceftriaxone, an antibiotic), acyclovir (an antiviral), and IV fluids. Id. at 6, 54, 316.

CT of brain

B.M. was sent for a CT scan of his brain. The interpreting radiologist, Marilee Benson, reported "No acute intracranial process is seen." Exhibit 3 at 194. However, the radiologists in this litigation said it was abnormal. Exhibit 54 (Dr. Wilson's report) at 2; Exhibit V (Dr. Zucconi) at 3-4.

From the emergency department, B.M. was transferred to the pediatric intensive care unit (PICU). He was unresponsive, hypertonic, and hyperreflexic.

[3] According to Dr. Kruer, Norton Children's Hospital is a tertiary care level facility. Exhibit C at 4; see also Resp't's Br. at 33 n.6.

Exhibit 3 at 6, 11, 53, 64. He had a fever (38.3 degrees Celsius). In the PICU, B.M. underwent a spinal tap, which is also known as a lumbar puncture. Exhibit 3 at 40-41.

Results of Spinal Tap

During the lumbar puncture, B.M. did not have elevated pressure. The spinal tap revealed 1 white blood cell, 5 red blood cells, 64 glucose and 118 protein. Exhibit 3 at 38; Exhibit C at 1. When the cerebrospinal fluid ("CSF") contains elevated amounts of proteins but few cells, the condition is called albuminocytological dissociation. Dorland's Illus. Med. Dict. 45 (33rd ed.); see also Resp't's Br. at 34.

The experts drew significantly different inferences from the CSF results. To Dr. Shafrir, the presence of a single white blood cell meant that B.M. did not have a viral infection. Exhibit 84 at 47. On the other hand, Dr. Kruer opined that the elevated protein level can be found in different conditions, including encephalitis. Exhibit BB at 3. Dr. Kruer also maintained that the lack of CSF pleocytosis and the lack of an elevated pressure made CNS vasculitis less likely. Exhibit BB at 4.

In addition to the spinal tap, the doctors ordered other laboratory tests. These included a respiratory pathogen panel (sometimes abbreviated "RPP") and standard blood work.

Respiratory Pathogen Panel / Coronavirus

The respiratory pathogen panel revealed that B.M. was infected with a strain of the coronavirus, OC-43. Exhibit 3 at 68; see also Exhibit 3 at 13 (discharge report). This strain of the coronavirus differs from the strain that caused the pandemic, starting in 2020. Exhibit P at 2. The detection of the coronavirus is a foundation for the Secretary's position that an infection caused B.M.'s encephalitis. See Resp't's Br. at 31.

Ms. Dotson's set of experts responded to the detection of encephalitis differently. To start, Dr. Gershwin asserts that the test was a false positive. Exhibit 18 at 4 ("the team at Norton's Children's Hospital was misled by the PCR"). However, Dr. Gershwin provides neither a reliable nor persuasive reason to negate the test results. More credibly, Ms. Dotson's other experts question whether the coronavirus can cause encephalitis.

Routine Blood Work

In the set of labs, a test for liver enzymes showed AST was high at 1273 and ALT was also high at 1271. Exhibit 3 at 37.

Again, Dr. Shafrir and Dr. Kruer disputed the meaning of elevated liver enzymes. Dr. Shafrir proposed that B.M.'s liver function was impaired possibly because of vasculitis. Exhibit 84 at 44. Dr. Kruer stated elevations in liver enzymes can occur for many reasons, including a coronavirus infection. Exhibit BB at 6. Dr. Kruer claimed: "Arguing that elevated liver enzymes indicate vasculitis is akin to arguing that a headache can only be explained by a brain tumor." Id.

2. December 3, 2014

Dr. Ruppe wrote that B.M.'s condition was "very concerning for meningoencephalitis or other CNS injury." Exhibit 3 at 53. The doctor also stated that B.M.'s "LP does not suggest infection, but would treat broadly. Coronavirus on RPP could be first evidence of viral syndrome." The doctor anticipated that an MRI, which was planned for later in the morning, could add information. Exhibit 3 at 53. B.M. was intubated in anticipation of the MRI. Exhibit 3 at 53.

December 3, 2014 Brain MRI

The interpreting radiologist, Karen Moeller, identified "multiple areas of signal abnormality." Exhibit 3 at 196. Based upon this information, Dr. Moeller considered "embolic infarctions or fat emboli syndrome." Id.

In this litigation, some experts reviewed the imaging from the December 3, 2014 brain MRI. Doctor Wilson basically concurred with Dr. Moeller's interpretation. Exhibit 54 at 3. Dr. Zucconi also agreed. Exhibit V at 4.

CT Angiogram

A CT angiogram was conducted on B.M.'s head and neck on December 3, 2014. Exhibit 3 at 199. A CT angiogram "is a minimally invasive form of angiography in which contrast material is injected intravenously through a small needle . . . and precise, detailed images of the vascular system are produced by computed tomography." Dorland's at 83. One purpose is to detect "abnormalities of cerebral circulation." Kathleen D. Pagana & Timothy J. Pagana, Mosby's Manual of Diagnostic and Laboratory Tests 930 (6th ed. 2018). For B.M., no vascular malformation was detected. Exhibit 3 at 189-90, 199.

The experts disputed the significance of the CT angiogram. Dr. Wilson stated that it was potentially abnormal. Exhibit 54 at 3-5. Dr. Wilson stated: "In the literature, 30% of patients with Varicella-Zoster virus (VZV) vasculitis have a normal angiogram because of predominant small-vessel involvement." Exhibit 54 at 5, citing Exhibit 57 at 107.[4] Dr. Shafrir asserted that people with vasculitis in their central nervous system can be negative on an angiogram. Exhibit 84 at 45, 48. On the other hand, Dr. Kruer maintained that the normal CT angiogram made a diagnosis of vasculitis less likely. Exhibit C at 3.

On December 3, 2014, a neurologist, Darren Farber (attending), reviewed the results from the December 3, 2014 brain MRI. Dr. Farber discussed with "the ICU [intensive care unit] team that the likely etiology for [B.M.'s] presentation was a CNS vasculitis. MRI findings are not suggestive of a demyelinating process, and a primary infectious process (encephalitis/meningitis) is not likely given NL [normal] CSF WBC." Exhibit 3 at 71. The neurologist did not close the door to other conditions as he added: "vasculitis may be assoc w/ certain viruses, etc." Id. "Will also [discuss with] [neurosurgery] need for formal angiogram." Id.

Echocardiogram

On December 3, 2014, an echocardiogram was performed. Exhibit 3 at 176. Dr. Lee noted that the echocardiogram showed: "Normal cardiac anatomy, chamber sizes, and systolic function. No evidence of RV hypertension. No pericardial effusion. No evidence of gross vegetations or thrombi. TTE does not rule out small vegetations or thrombi." Id.

MR Angiogram

Dr. Farber consulted Dr. Dashti and they agreed to proceed with an "emergent MRI Angiography today." Exhibit 3 at 368. The purpose was to rule out vasculitis. Id. at 189. There was "No angiographic evidence of vasculitis." Id. at 190; accord Exhibit 3 at 330.

In the litigation, Dr. Wilson reviewed the MR Angiogram and concurred this study was normal. Exhibit 54 at 3. Dr. Wilson attempted to reconcile the results of this angiogram with the previous angiogram, which Dr. Wilson described as potentially abnormal. Dr. Wilson hypothesized that either the earlier CT angiogram had technical limitations that suggested an irregularity that did not

[4] Maria A. Nagel & Andrew N. Bubak, Varicella Zoster Virus Vasculopathy, 218 J. OF INFECTIOUS DISEASES 107 (2018); filed as Exhibit 34.

actually exist or B.M. improved between studies. Id. at 3-4. Dr. Zucconi said the MR Angiogram was normal. Exhibit V at 6.

After the MRI and MR angiogram were completed, specialists in pediatric infectious diseases, Dr. Rabalais (attending) and Dr. Rebecca Hart (resident), saw B.M. They wrote that the MRI and MR angiogram made an infectious etiology "less likely." Exhibit 3 at 97. They noted the presence of coronavirus on the respiratory pathogen panel and stated. "Unclear significance in relation to the brain lesions." Id. at 99. The infectious disease specialists changed the antibiotics to vancomycin, meropenem, and Bactrim. Id. at 98-99. The infectious disease specialists also discontinued acyclovir. Id. at 98.

3. December 4, 2014

A rheumatologist, Kenneth Schikler, saw B.M. Dr. Schikler was concerned about "Small Vessel CNC [sic] vasculitis which can be secondary to infectious, non-infectious inflammatory autoimmune or autoinflammatory diseases as well as metabolic/mitochondrial disorders." Exhibit 3 at 149. This doctor recommended a series of tests, including a test for von Willebrand re: antigen, in the context of potentially starting cyclophosphamide. Id.

Cyclophosphamide is a medication to treat various types of cancer. Dorland's at 451. It can also be used as an "immunosuppressive agent . . . in the treatment of certain diseases with abnormal immune function." Id. A trademarked preparation of cyclophosphamide is called "Cytoxan." Dorland's at 462.

On December 4, 2014, a test for von Willebrand related antigen was ordered by Dr. Morgan and performed. Exhibit 3 at 171 and 260. Von Willebrand factor is a "glycoprotein synthesized in endothelial cells… that circulates complex to factor VIII; it mediates adhesion of platelets to damaged epithelial surfaces." Dorland's at 670.

> Von Willebrand factor (vWF) antigen is a plasma protein that is synthesized by megakaryocytes and endothelial cells and is released when vascular endothelium is damaged or inflamed. As a result, this vessel-derived factor may be more responsive to changes in vasculitic disease activity and less influenced by systemic stimuli than other inflammatory markers.

Exhibit 98 (Cellucci) at 734-35.[5]

For B.M., the results for Factor VIII related Ag were elevated at greater than 150. Exhibit 3 at 171. Dr. Schikler noted that based on the "elevated factor VIII re Ag which is indicative of vasculitis, in spite of the 'nl' arteriogram (which is not unusual in Small Vessel CNS Vasculitis svCNS V) and lack of brain tissue from a biopsy, and [B.M.'s] condition I have discussed this with Dr. Farber and agree that aggressive Rx for [svCNS] vasculitis is appropriate." Id. at 150.

An important consultation with the pediatric infectious disease specialists occurred on December 4, 2014. Dr. Woods (attending) was attempting to determine the etiology for B.M.'s altered mental status. The "MRI/MRA with multiple lesions throughout cerebrum, cerebellum [and] brainstem [were] concerning for embolic infarct vs. vasculitis, less likely infectious etiology." Exhibit 3 at 343. Dr. Woods noted that B.M. is "Coronavirus positive—there are brief accounts in the literature of presenting with seizure activity or encephalopathy, but case reports are minimal and would not be expected to present with MRI finding seen." Id. The doctor offered another idea: "Postinfectious/post-viral encephalopathy is also a possibility. [B.M.] has received a varicella vaccine (his first dose) in the last month prior to presentation, and there are some minimal case reports of varicella encephalitis and vasculitis, although none are reported after vaccination in children." Id.

The treatment recommendations illustrate how the doctors were struggling to treat B.M., as they weighed the advantages and disadvantages of different approaches. Id. at 343-44. The impression was that B.M.'s process "is unlikely infectious in nature though it could be a post-infectious inflammatory syndrome. VZV-related vasculitis is not impossible, but unlikely." Id. at 345.

Commentary on the December 4, 2014 Report from the Infectious Disease Specialist

Although Dr. Woods had indicated that the results of the MRI suggested an infectious etiology was "less likely," Dr. Zucconi disagreed. Exhibit V at 9; Exhibit Y at 2.

[5] Tania Cellucci & Susanne M. Benseler, Diagnosing central nervous system vasculitis in children, 22 CURRENT OPINIONS IN PEDIATRICS 731 (2010); filed as Exhibit 98.

As part of his recommendations, the infectious disease expert ordered testing for varicella zoster virus. Exhibit 3 at 344.

Results of Varicella Zoster Virus Testing

Type of Test	Result	Date Result Returned	Page within Exhibit 3
CSF PCR	Unable to Perform	12/7/2014	472, 497
Bone marrow PCR	Negative	12/9/2014	1516
CSF antibody	Negative	12/12/2014 12/18/2014	1535-36 1548
Serum PCR	Negative	12/16/2014	303, 592

A pediatric neurologist conferred with B.M.'s parents. Dr. Farber informed them that B.M.'s "MRI is suggestive of a small vessel vasculitis, and often times the angio may be [normal] in this situation." Exhibit 3 at 369. Based upon this information, B.M.'s parents asked whether B.M. could be transferred to Toronto's Children's Hospital, whose staff has "the most experience w/ CNS vasculitis in children, and we discussed that [B.M.] is not stable enough for transfer. [But,] Toronto's protocol is well published, and that we will start Cytoxan." Id.

Part of the neurologist's consultation concerned whether to biopsy B.M.'s brain. "A biopsy is the most definitive test to [diagnose] a small vessel CNS vasculitis, and is [recommended if] the formal angio is [normal] but it is an invasive procedure, and will not change our current management." Id. B.M.'s parents and his medical team "decided to hold off on this for now." Id.

In the meantime, the neurologist wanted to obtain another MRI of B.M.'s brain tomorrow "to assess for new areas of ischemia, cerebral edema or [hemorrhage]." Id. The neurologist also wanted to "maximize his immunosuppression [treatment] and will start IVIG." Id.

The general progress notes agree with the pediatric neurology notes from December 4, 2014 that the working diagnosis is a small vessel vasculitis. Exhibit 3

at 368. Dr. Farber noted that B.M.'s "neuro exam unchanged, however has developed autonomic instability, suggestive of a disease progression." Id. at 369. Dr. Farber discussed the need for a brain biopsy with B.M.'s parents because a biopsy "is the most definitive test to [diagnose] a small vessel CNS vasculitis, and is [recommended if] the formal angio is [normal]." Id. Dr. Farber also discussed the need for anticoagulation because B.M. did not appear to have a primary thrombo-embolic disease, and Dr. Farber was "concerned for the potential of bleeding given his high ischemia burden." Id.

4. December 5, 2014

The pediatric rheumatologist, Dr. Schikler, considered the appropriate treatment course for B.M. in light of uncertainties:

> Based on the elevated factor VIII re Ag which is indicative of vasculitis, in spite of the "nl" arteriogram (which is not unusual in Small Vessel CNS Vasculitis svCNSV) and lack of brain tissue from a biopsy, and [B.M.'s] condition I have discussed this with Dr. Farber and agreed this aggressive Rx for svCNS vasculitis is appropriate.

Exhibit 3 at 150.

Dr. Schikler "discussed with [B.M.'s] mom and dad the drug itself and its side effects and risks and they understand why it is being recommended and agreed to its use." Id. Accordingly, the doctor ordered Cytoxan and prednisone. Id.

Second Brain MRI on December 5, 2014

As the neurologist had ordered on December 4, 2014, B.M. had another MRI on December 5, 2014. Exhibit 3 at 206. The MRI revealed: "Multiple lesions are again visualized scattered throughout both cerebral hemispheres.… There are also lesions in the basal ganglia brainstem and cerebellum. The corpus callosum is also involved." Id. The impressions of the radiologist (Dr. Moeller) included: "The differential diagnosis includes an atypical ADEM or perhaps a small vessel vasculitis." Id. at 207.

The pediatric neurology follow up on December 5, 2014 stated that: "Brain MRI was essentially stable, no significant new areas of cytotoxic edema." Exhibit 3 at 408. "Today had lengthy [discussion with] family along [with] peds heme-onc, we discussed that his ANC was dropping for reasons that were not entirely

clear, but likely related to his underlying autoimmune/rheumatolic disorder, and therefore would obtain a bone marrow biopsy/aspirate." Id. Additionally, "also [discussed with] parents that on his abd US, liver showed ? Areas of inflammation (LFTs have been improving), ? Liver biopsy as well at some point in his workup . . . given his low PLT, and small area of hge on MRI, would not place him on any anti-LPT TX or anti-coagulation."[6] Id. "[Neuro] exam stable today, no significant changes." Id.

The experts drew different conclusions from the second MRI. Dr. Wilson stated that abnormalities on the December 5, 2014 brain MRI included T2 or "gradient" images that are sensitive to hemorrhage. Exhibit 54 at 4; Pet'r's Br. at 21. Dr. Shafrir compared the results of the two MRIs. In his opinion, the lack of progression was inconsistent with a viral etiology. Exhibit 84 at 48; Pet'r's Br. at 29. In contrast, Dr. Zucconi opined that the prominent areas of T2 signal hyperintensity without a corresponding diffusion abnormality were most compatible with a viral encephalitis. Exhibit V at 8-9; see also Resp't's Br. at 32.

The infectious disease specialist, Dr. Rabalais, saw B.M. on December 5, 2014. His impressions included:

1. Stable neurologically with as yet unexplained multiple acute lesions in brain thought to be a vasculitic process
2. Coronavirus infection
3. [Status/post] varicella immunization: PCR pending
4. Continued fall in WBC, [platelets] and [hemoglobin] are of concern

Exhibit 3 at 397. His recommendations show that B.M.'s medical team was balancing several factors.

1. Acyclovir dosing as in Dr. Hart's note above; if renal toxicity along with other medications is of concern, would stick with low dose. Consider stopping [acyclovir] if blood PCR is negative. I think there is a very very low likelihood that this CNS process represents a varicella vaccine complication, but until we have a definitive answer, it seems reasonable to continue for now.
2. Continue [vancomycin] and Meropenem for now. All cultures are negative and there has been no progression of the lesions to suggest multiple septic

[6] It is not readily apparent in the record whether 'hge' is an abbreviation for hemorrhage or not.

emboli with evolution to small brain abscesses so again, the likelihood of this being a bacterial infection is very low.
3. Consider bone marrow exam given fall in hematologic parameters to rule out leukemia as precipitating event for these lesions.

Id. at 397. A bone marrow biopsy showed no evidence of leukemia. Exhibit 3 at 175, 240-42 (Dec. 6, 2014); Pet'r's Br. at 13.

As the doctors had planned with B.M.'s parents, Cytoxan was started. Exhibit 3 at 429; Pet'r's Br. at 13. Dr. Shafrir interpreted the prescription of Cytoxan as indicating that the "treating physician did not think that it is acute viral encephalitis. The[y] actually took a bold move and started to treat the patient immediately with high do[s]es methylprednisolone and cyclophosphamide." Exhibit 84 at 46; Pet'r's Br. at 31. Dr. Shafrir reasoned: "if he had acute viral encephalitis, one would expect this treatment to make the patient worse. They would not have done that if they would have any worry about acute viral encephalitis." Id. On the other hand, the Secretary argues: "Dr. Shafrir has provided no evidence for the notion that B.M. would not have been given Cytoxan by his physicians if he had had encephalitis." Resp't's Br. at 34.

5. December 6, 2014

The neurologist, Dr. Farber, saw B.M. and assessed him as "slightly improved" on examination. Exhibit 3 at 444. Dr. Farber's note again shows the complexity of the case: "Current working diagnosis is a small vessel vasculitis. Patient is currently being treated with steroids, IVIG and Cytoxan to cover for vasculitides and demyelinating disorders as his presentation and workup is not classic for either." Id.

6. December 7, 2014

An infectious disease specialist saw B.M. The assessment begins by stating that there are "multiple possible etiologies" for B.M.'s "altered mental status." Exhibit 3 at 471-72. Dr. Hart recounted that the "Current thinking given [patient's] Factor VIII related antigen levels is that this may represent a small vessel CNS vasculitis vs. Demyelinating process. [Patient] has no evidence of vasculitis on cerebral angiogram but per Dr. Schikler this is not unexpected." Id.

The note from the infectious disease specialist from December 7, 2014 also memorializes that B.M. was receiving various medications: B.M. is now status post "IVIG x 1 on 12/4, 3 doses of pulse IV Solu-Medrol, and Cytoxan on 12/5." Id. at 472.

This December 7, 2014 note echoed the earlier December 3, 2014 note in that both discussed that B.M. was coronavirus positive and that he had received a varicella vaccine in the month before presentation. The December 7, 2014 note added that B.M.'s "VZV PCR in the serum is negative (unable to obtain on CSF). Id. at 472.

7. December 8-10, 2014

B.M. was more responsive and was extubated. Exhibit 3 at 151-52; Pet'r's Br. at 13; Resp't's Br. at 5.

Flow Cytometry

An immunologist was consulted because B.M. was having persistent leukopenia. ("Leukopenia" means the person has a reduction in the number of white blood cells. Dorland's at 1015 (defining "leukocyte"), 1017 (defining "leukopenia" in reference to leukocytes.) The immunologist ordered flow cytometry. "Flow cytometry" measures and characterizes cells and cellular constituents. Dorland's at 461. In Dr. Gershwin's view, flow cytometry is complex and fraught with error. Exhibit 47 at 4; Pet'r's Br. at 25.

B.M.'s flow cytometry was abnormal. He lacked T-memory cells. Exhibit 3 at 12-13, 229-30, 1509-10. In the opinion of Dr. Kruer, B.M.'s immunodeficiency would predispose him to a neural invasion from a coronavirus. Exhibit C at 4; Exhibit P at 2-3; Exhibit X at 3-4.

A new pediatric neurologist, Vinay Puri, began treating B.M. on December 8. He stated that B.M. was "stuporous" and had "left sided weakness." Exhibit 3 at 525. Dr. Puri assessed B.M. as having "ADEM with a small vessel vasculitic component." Id. at 524. He added that: "This could be related to Corona virus." Id. at 525.

A new pediatric rheumatologist started to see B.M. on December 9, 2014. Dr. Kara Murphy Schmidt repeated what the neurologist had said the day before – the "working diagnosis is ADEM with small vessel vasculitic component." Exhibit 3 at 559. Dr. Murphy Schmidt also requested a repeat Von Willebrand factor antigen test to assess for improvement in vasculitis. Exhibit 3 at 559.

B.M.'s history in the pediatric intensive care unit was summarized when he was moved from the PICU to the pediatric floor. See Exhibit 3 at 565-70. At the time of transfer, the current differential diagnosis was "ADEM vs small vessel vasculitis." Id. at 566

8. December 11-15, 2014

Another flow cytometry was ordered on December 11, 2014. The results were again abnormal. Exhibit 3 at 229-30. An immunologist, Gerald Lee, who saw B.M. on December 15, 2014 suggested that B.M.'s immunodeficiency was likely secondary due to immunosuppression therapy. Id. at 176.

On December 12, 2014, Gregory Barnes became the attending neurologist. An advanced practice nurse on Dr. Barnes's team stated that the "MRI findings [were] concerning for ADEM alongside a small cell vasculitic process post viral illness." Exhibit 3 at 586. For diagnosis, Dr. Barnes wrote that: "The child likely has ADEM." Id.

A pediatric infectious disease doctor also stated that: "Diagnosis felt to be consistent w/ small vessel CNS vasculitis vs. ADEM." Exhibit 3 at 591 (Dec 12, 2014). Dr. Hart ruminated on potential causes:

> Infectious etiologies are considered unlikely as [patient] has had normal blood and CSF [cultures] (as well as normal CX from B.M.A), normal echo and CTA. Post-infectious or post-vaccine response is a possible cause for ADEM and vasculitis, and Coronavirus (for which [patient's] RPP was positive) has been reported to cause ADEM with current infection in some case reports. While [patient] did receive several vaccinations (including varivax, MMR, flu) in the month prior to presentation, there is less evidence for vaccinations as a cause of ADEM.

Id.

The attending doctor (Dr. Woods) noted that test for various infectious organisms were negative. "No evidence of [herpes simplex virus] or VZV infection, thus acyclovir can be discontinued." Exhibit 3 at 592.

Dr. Woods concluded: "Best estimate of diagnosis is small vessel vasculitis +/- ADEM as a postinfectious manifestation of coronavirus infection. Recent vaccines are unlikely to be the triggering event based on epidemiologic studies." Id.

Discharge on December 15, 2014

B.M. was discharged from Norton Children's Hospital to a rehabilitation hospital on December 15, 2014. Exhibit 3 at 6, 14. Dr. Puri, who authored the report, reviewed the lesions in B.M.'s brain and stated that the "process is likely viral [in] its etiology." Id. at 15. The discharge report stated that B.M. "was treated aggressively upon admission with IV Solu-Medrol, IVIG and Cytoxan. The patient is now manifesting a neutropenia secondary to Cytoxan." Id. Dr. Puri also stated: "no evidence for a CNS vasculitis based on formal angiography." Id.

C. Rehabilitation, Rehospitalization, and Second Rehabilitation[7]

B.M. stayed at an inpatient rehabilitation facility, Frazier Rehab Institute, for five days. Exhibit 5 at 14-15 (December 15-19, 2014).

Due to a high fever, B.M. was readmitted to the hospital from December 19 through December 23, 2014. During this stay, he tested negative for the coronavirus. Exhibit 3 at 1576 (Dec 19, 2014). He was described as developmentally delayed. Exhibit 3 at 1559-60, 1562.

For the next month, B.M. had a second inpatient rehabilitation. For this month, B.M. received daily physical, occupational, and speech therapy. When he was discharged, B.M. was sitting independently and standing with hands-on assistance. Exhibit 5 at 10-11.

D. Remainder of 2015

B.M. followed up with the pediatric rheumatologist, Kara Schmidt. Her assessment was "ADEM with small vessel vasculitic component." Exhibit 14 at 2 (Jan. 26, 2015). Around this time, B.M. was receiving speech therapy, physical therapy, and occupational therapy three times per week. Exhibit 4 at 9-17.

At a stroke clinic in February 2015, B.M. saw his neurologist, Dr. Puri. He had left-sided weakness and increased tone. He could not walk independently. While on Keppra, he had not had any seizures since his hospitalization.

[7] The medical records created after B.M. was discharged from Norton Children's Hospital are relatively less valuable in determining whether the varicella vaccine harmed him. Thus, these records are described more summarily. For additional details, see Pet'r's Br. at 18-19; Resp't's Br. at 8-11.

Assessments included vasculopathy and cerebral palsy. Dr. Puri recommended repeating the immunologic testing, EEG, and MRI. Exhibit 8 at 19-22.

The repeated immunologic testing included another flow cytometry. The results showed decreased absolute numbers of T cells and B cells, suggesting a primary or secondary immunodeficiency. Exhibit 3 at 1823-24, 1849-51.

The repeated neurologic testing occurred in April 2015. The EEG was within normal limits. Exhibit 8 at 23-24. The brain MRI showed "near-complete interval resolution of multiple lesions throughout both cerebral hemispheres and cerebellum compared to December 2014 suggestive of a resolved ADEM or perhaps an unusual resolved viral encephalitis." Exhibit 8 at 31.

This MRI was reviewed by Dr. Puri in the stroke clinic. B.M.'s parents stated that he was making significant gains in development, including pulling himself up and crawling. However, he could not walk independently. Exhibit 8 at 14 (May 7, 2015). Dr. Puri wrote that the "neuroimaging of the brain demonstrated multiple small areas of infarction believed to be secondary to a viral encephalitis/vasculitis caused by Coronavirus." Id. The parents mentioned that B.M. was scheduled to see immunology again. The assessment was largely the same as in February 2015 --- such as cerebral palsy. Dr. Puri stated that the cerebral palsy was milder than expected based upon B.M.'s initial presentation. Id. at 17-18.

Another flow cytometry happened the next month. Although the results were similar to the February 17, 2015 flow cytometry, the "percentage and total number of CD4+ T-cells has increased resulting in an normal CD4:CD8 ratio and total T-memory cells are within expected range." Exhibit 12 at 9.

Dr. Lee saw B.M. about three months later. Dr. Lee wrote that he "consulted on [B.M.] while hospitalized for encephalomyelitis following coronavirus infection. He was treated with Cytoxan and corticosteroids and developed lymphopenia, which at the time I felt was more secondary to his treatment rather than an immune deficiency." Exhibit 12 at 2 (May 18, 2015). Based, in part, on the results from a flow cytometry, Dr. Lee stated that B.M.'s lymphopenia was "improving." Id. at 6. Dr. Lee reiterated he suspected that the lymphopenia was "secondary to immune suppression rather than primary immune deficiency." Id.

In December 2015, B.M. returned to the stroke clinic. He was no longer taking Keppra and had not had any seizures. Exhibit 8 at 8, 18. Dr. Puri, the

neurologist, observed that B.M. had speech, language, and motor delays, and was likely to have long-term motor deficits. The history included an "acute central nervous system vasculopathy which I believe was viral in etiology." Id. at 12.

E. 2016 and More Recent

"B.M. continued to be followed by multiple specialists and engaged in rehab." Pet'r's Br. at 19. The parties did not further summarize medical records. See Pet'r's Br. at 19; Resp't's Br. at 10-11.

Ms. Dotson averred that B.M. did not see an immunologist after 2015. Exhibit 115 (affidavit, signed Apr. 15, 2024) ¶ 5. She also stated that B.M. has not tested positive for the pandemic's coronavirus. SARS-CoV-2. Id. at ¶ 7.

II. Procedural History

A. Development before Expert Reports

Represented by attorneys from Maglio Christopher and Toale, Ms. Dotson alleged various vaccines caused B.M. to suffer ADEM. Pet., filed May 15, 2017. Ms. Dotson supported her claim by filing medical records and affidavits.

The Secretary reviewed this material and recommended against compensation. Resp't's Rep., filed Nov. 9, 2017. The Secretary challenged Ms. Dotson's claim that B.M. suffered from ADEM and argued that, even if B.M. did suffer from ADEM, the evidence in the record did not support a finding that the ADEM was caused-in-fact by the vaccines B.M. received. Part of the deficiency, according to the Secretary, was that Ms. Dotson did not present expert opinion linking the vaccination to the alleged condition. Id. at 10-11.

Because it seemed likely that Ms. Dotson would attempt to present an opinion from an expert, a set of instructions for experts were proposed. Order, issued Nov. 27, 2017. After neither party interposed any objection, the instructions became final. Order, issued Dec. 12, 2017.

Ms. Dotson did not speedily present a report from an expert. See First Order to Show Cause, issued Apr. 29, 2019 (recounting reasons for not filing an expert report). During this time, an attorney from Maglio Christopher & Toale was

replaced as counsel of record. Attorney Richard Gage became counsel of record on August 14, 2018, and has represented Ms. Dotson since then.[8]

Slightly more than two months after Mr. Gage's appearance, the Secretary sought dismissal due to the lack of an expert report. Resp't's Mot. to Dismiss, filed Nov. 27, 2018. Mr. Gage stated that he had become counsel of record on August 14, 2018, and that he anticipated that he would file a report from Lawrence Steinman after the first of the year. Pet'r's Status Rep., filed Nov. 28, 2018. Based upon this representation, the Secretary's motion to dismiss was denied. Order, issued Dec. 6, 2018. This order set a deadline of January 7, 2019 for Ms. Dotson to provide more information about a report from Dr. Steinman.

B. Dr. Gershwin's Initial Reports

Consistent with the representation in the November 28, 2018 status report, Ms. Dotson proposed filing a report from Dr. Steinman in 60 days. Pet'r's Status Rep., filed Jan. 7, 2019. Ms. Dotson was afforded the time she had requested. Order, issued Jan. 8, 2019 (setting deadline of March 8, 2019). On the deadline, Ms. Dotson requested additional time. Pet'r's Mot., filed Mar. 8, 2019. Ms. Dotson was again granted the amount of time she had requested. Order, issued Mar. 13, 2019.

Ms. Dotson did not file a report from Dr. Steinman. Instead, Ms. Dotson submitted a letter from M. Eric Gershwin. Exhibit 15. This statement from Dr. Gershwin asked for more information and in the statement, Dr. Gershwin did not opine that any vaccination harmed B.M. Due to the multiple unsuccessful efforts to support the case with an expert report, Ms. Dotson was faced with a dismissal of her case. First Order to Show Cause, issued Apr. 29, 2019.

Ms. Dotson supported her claim by filing a six-page report from Dr. Gershwin, dated May 14, 2019. Exhibit 18.[9] (This decision treats the May 14, 2019 report as Dr. Gershwin's first report.) Dr. Gershwin opined that a varicella vaccine caused B.M. to suffer vasculitis in his central nervous system. Id. at 6. In discussing the events in B.M.'s medical history, Dr. Gershwin was "concerned

[8] Before Mr. Gage became counsel of record, a motion for an award of attorneys' fees and costs on an interim basis was filed. This motion was denied. Interim Fees Decision, issued Feb. 28, 2019.

[9] Throughout the litigation, the parties filed medical articles on which their experts relied. The dates of those various submissions are not detailed in this Decision. Ms. Dotson filed two exhibits as exhibit 18. Dr. Gershwin's expert report is ECF No. 55.

about two potential factual errors in the medical records that will lead to incorrect interpretation of the data and therefore an incorrect diagnosis in this youngster." Id. at 4. The first potential error was that in Dr. Gershwin's opinion, B.M. did not have an immune deficiency. Id. The second potential error was that in Dr. Gershwin's opinion, B.M. did not suffer from an infection with a coronavirus. Id. at 4-5.

While describing vasculitis, Dr. Gershwin cited an article by Twilt and Bender. Id. at 5 (reference 16). The Twilt and Benseler article is about CNS vasculitis in children. Exhibit 36.[10] Dr. Gershwin wrote that the "mechanism of varicella-induced vasculopathy appears to be that of vasculitis and the authors note that the most common etiology is infection and they emphasize varicella." Exhibit 18 at 5.

The Secretary argued that Ms. Dotson's case should be dismissed. Resp't's Mot., filed May 29, 2019. In the Secretary's view, Ms. Dotson "has failed to meet the requirements for compensation for a causation-in-fact injury claim." Id. at 3. This lack of proof was due, in part, because "Dr. Gershwin's reports are patently insufficient to meet petitioner's burden of proof." Id.

Ms. Dotson's response to the Secretary's May 29, 2019 motion to dismiss took two forms. First, Ms. Dotson argued that the Secretary's motion to dismiss without an evidentiary hearing was procedurally improper because the only way to dismiss a case without a hearing was through summary judgment. Pet'r's Resp., filed June 12, 2019.[11] Second, Ms. Dotson added another report from Dr. Gershwin. Exhibit 40. This June 18, 2019 report is approximately one page. Although Dr. Gershwin asserts that this supplemental report "will focus on the three (3) Althen prongs," id. at 1, Dr. Gershwin wrote approximately one sentence on Althen prong one and two sentences on Althen prong two. The balance of the report was about Althen prong three.

Dr. Gershwin's reports were deemed not satisfactory. Ms. Dotson, thus, faced dismissal again. Second Order to Show Cause, issued Sep. 6, 2019. The

[10] Marinka Twilt & Susanne M. Benseler, The spectrum of CNS vasculitis in children and adults, 8 NATURE REV. RHEUMATOL. 97 (2012); filed as Exhibit 36.

[11] The Federal Circuit later rejected this argument. Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2020).

Second Order to Show Cause identified problems that continue to impair Ms. Dotson's case.

A problem was that Dr. Gershwin may not have disclosed a theory explaining how the varicella vaccine can cause vasculitis. Second Order to Show Cause, issued Sep. 6, 2019, at 3. The undersigned "stretch[ed] what Dr. Gershwin [had] written" to understand that Dr. Gershwin may have been proposing a theory based upon "either a varicella infection or a hypersensitivity reaction. Both are problematic." Id. at 3. First, although the varicella vaccine might lead to a varicella infection as a matter of theory, Ms. Dotson could not prevail upon this theory because Dr. Gershwin wrote: "I submit that there is no evidence of infection." Exhibit 18 at 4. Alternatively, Dr. Gershwin may have proposed a hypersensitivity reaction. But, this theory seemed incapable of resulting in an award of compensation to Ms. Dotson because (a) "Dr. Gershwin has not cited evidence that B.M. suffered an allergic reaction" and (b) "the latency between the vaccination . . . and the date of hospitalization . . . (25 days) appears to exceed the amount of time expected for an allergic reaction to manifest." Second Order to Show Cause at 4. Thus, Ms. Dotson was given another opportunity to present "a comprehensive, complete, and reliable report from Dr. Gershwin." Id. Ms. Dotson was directed to have Dr. Gershwin comply with the Instructions and to submit "a single, stand-alone report." Id.

Ms. Dotson attempted to comply by filing another report from Dr. Gershwin. Exhibit 47. This October 2, 2019 report is approximately eight pages. As permitted in the Second Order to Show Cause, Dr. Gershwin copied much of the material from his previous reports into this report. For example, Dr. Gershwin continued to deny that B.M. suffered from "immune deficiency" and Dr. Gershwin continued to dispute B.M. was infected with a coronavirus. Id. at 4. Dr. Gershwin also maintained that B.M suffered from "small vessel vasculitis." Id.

As for the theory by which a varicella vaccine can cause small vessel vasculitis, Dr. Gershwin's October 2, 2019 report was not a model of clarity. Under the heading "Theory, Althen 1," Dr. Gershwin wrote approximately four paragraphs. Exhibit 47 at 5-6. However, discerning a theory within this section is difficult. For example, Dr. Gershwin wrote: "The 'theory' is that Varicella antigens, whether from a live virus or from a live viral Varicella vaccine can cause CNS vasculitis. The cause and effect relationship between the Varicella antigen and CNS vasculitis is known and accepted by the medical community." Id. at 6. For the proposition, that the medical community accepts this relationship Dr. Gershwin cited a series of case reports as well as one article, Wise. Under the heading, "Althen III," Dr. Gershwin wrote another paragraph and within this

paragraph, Dr. Gershwin discussed timing in the context of molecular mimicry. Id. at 6.

In conjunction with the submission of Dr. Gershwin's October 2, 2019 report, Ms. Dotson amended her petition. Ms. Dotson now alleged the November 7, 2014 varicella vaccine caused B.M. to suffer "the immune-mediated injury of cerebral vasculitis." Am. Pet., filed Oct. 3, 2019, ¶ 5.

Dr. Gershwin's October 2, 2019 report appeared adequate.[12] Thus, a status conference was held.

C. Development of Additional Expert Opinions

During the October 23, 2019 status conference, the parties discussed Dr. Gershwin's most recent report. It appeared that Dr. Gershwin was relying upon the theory of molecular mimicry. Order, issued Oct. 23, 2019. Thus, the Secretary was directed to respond. Id.

The Secretary responded to Dr. Gershwin's opinions by presenting a report from Dr. Kruer, which is approximately four pages. Exhibit C. Dr. Kruer made three points and added one request. First, Dr. Kruer asserted B.M. likely suffered an infection with a primary coronavirus. Id. at 2. Second, Dr. Kruer stated that a "diagnosis of vasculitis was never confirmed." Id. at 3. Third, Dr. Kruer opined that B.M. suffered a primary immunodeficiency. Id. Dr. Kruer's request was to obtain original images of various studies. Id.

In due course, the images were obtained and provided to Dr. Kruer. Dr. Kruer wrote a second report, which was slightly longer than three pages. Dr. Kruer presented opinions about the images. Exhibit P at 1-3. Dr. Kruer also commented upon the Althen prongs. In Dr. Kruer's opinion, Dr. Gershwin "has not proffered a theory of causality." Id. at 3. Dr. Kruer also posited that it was "far more likely than not B.D.'s symptoms were due to the Coronavirus OC43 in the context of his underlying immunodeficiency." Id. at 4.

In the ensuing status conference, Ms. Dotson expressed an intention to retain a radiologist to review images. Ms. Dotson also planned to submit a short supplemental report from Dr. Gershwin. See Order, issued June 3, 2020.

---

[12] Whether Mr. Gage and Dr. Gershwin should be compensated and what a reasonable amount of compensation would be for the largely ineffective efforts may depend upon the Secretary's position. See Vaccine Rule 13(a)(3).

Ms. Dotson presented a seven-page report from David Wilson. Exhibit 54.[13] Dr. Wilson presented his interpretations of various imaging studies. Id. at 2-4. From this information and a limited amount of clinical information, Dr. Wilson concluded that the most likely explanation for B.M.'s condition was a "vasculopathy which may have been of infectious or immunogenic origin; however this vasculopathy was almost certainly not caused by the cited pathogen OC43." Id. at 4. Dr. Wilson acknowledged that from "an imaging perspective, this is a challenging case." Id. Dr. Wilson's report suggested different possible diagnoses of 1) a vasculopathy, 2) a cerebritis/cerebellitis caused by an infectious agent, 3) acute demyelinating injury, either ADEM or AHEM, and 4) embolic stroke. Id. Dr. Wilson opined that since "increased signal on [diffusion-weighted imaging] can be seen in demyelinating disease, and the relationship of injury to vaccine administration, ADEM/AHEM is an important consideration in this case." Id. at 6. Dr. Wilson continued to state that the DWI signals seen are more consistent with acute stroke than demyelinating disease. Id.

In conjunction with Dr. Wilson's report, Ms. Dotson submitted another report from Dr. Gershwin. In this one-page report, Dr. Gershwin essentially says that he agrees with Dr. Wilson's opinions and maintains his previously expressed opinions. Exhibit 76.

In the next status conference, because Ms. Dotson had presented a report from Dr. Wilson, the Secretary expressed an interest in obtaining a report from a neuroradiologist. The Secretary also wanted to obtain a supplemental report from Dr. Kruer. Order, issued Oct. 19, 2020.

The Secretary filed these two reports on January 6, 2021. Dr. Zucconi's January 6, 2021 report is nine pages. Like Dr. Wilson, Dr. Zucconi reviewed images from various studies on B.M. Exhibit V at 2-6. Dr. Zucconi considered different diagnoses. Ultimately, Dr. Zucconi concluded that "[a]cute viral encephalitis is considered most likely" with HCoV-OC43 the "leading pathogen." Id. at 9.

The second report filed on January 6, 2021 was Dr. Kruer's next report, which is approximately six pages. Dr. Kruer stated that "Dr. Gershwin's report did

[13] Dr. Wilson's first report was originally filed on September 30, 2020. But, one page was illegible and it was struck. The legible version of Dr. Wilson's first report was filed on October 7, 2020.

not contain new assertions." Exhibit X at 1. Thus, Dr. Kruer's opinions were directed to Dr. Wilson.

With respect to diagnosis, Dr. Kruer found common ground in how Dr. Wilson interpreted B.M.'s imaging. "I agree with Dr. Wilson's assessment: BM's neuroimaging is highly unusual. It is not 'typical' of anything, and so we are very likely to be dealing with either a rare disease, or an atypical manifestation of a common disease, or some combination of the two." Id. at 1. With this caveat, Dr. Kruer confirmed his earlier opinion that the "most likely diagnosis" is "an atypical coronavirus OC43 encephalitis in the context of an underlying immunodeficiency." Id. Dr. Kruer explained the bases for this opinion over the next four pages. Id. at 1-5.

Dr. Kruer also addressed the Althen factors briefly. He opined that the work of Dr. Gershwin and Dr. Wilson were not sufficient to show that the varicella vaccine caused B.M. to suffer vasculitis. Instead, the evidence was more consistent with an OC43 infection. Id. at 5-6.

Another status conference was held. Ms. Dotson stated that she planned to speak with Dr. Gershwin and Dr. Wilson about whether either or both would respond. Ms. Dotson also inquired about setting a date for a hearing. However, a hearing would not be set until after the parties advocated through briefs, which would be after the experts had finished disclosing their opinions. See Order, issued Jan. 15, 2021.

Ms. Dotson submitted another report from Dr. Gershwin, which was approximately two pages. In conclusion, Dr. Gershwin "agree[d] B.M.'s symptomologies are unusual but that they are consistent with a VZV vasculopathy." Exhibit 77 at 2.

A March 12, 2021 scheduling order required each party to act. Ms. Dotson was directed to file updated medical records. The Secretary was directed to state whether a response to Dr. Gershwin's most recent report was required. The Secretary did so and wanted to file additional reports. Resp't's Status Rep., filed March 26, 2021.

The Secretary filed another pair of reports on May 21, 2021. Dr. Zucconi's two-page report addresses why a varicella infection was unlikely and why the imaging supports acute viral encephalitis. Exhibit Y. Dr. Kruer challenges Dr. Gershwin's opinion that B.M. suffered from VZV vasculopathy. Exhibit Z.

Due to the relative repetitiveness and brevity of the most recent reports, it appeared that the case was likely to proceed to the briefing stage. As part of this process, Ms. Dotson filed some updated medical records as well as school records. Exhibits 80-82.

D. Addition of Dr. Shafrir and Development of More Expert Opinions

In the June 23, 2021 status conference, Ms. Dotson proposed adding another expert, a neurologist. In her view, Dr. Wilson's experience as a neuroradiologist did not exactly match the background of a neurologist. Although the Secretary did not object---provided he was entitled to respond, the Secretary noted that in fall 2020, Mr. Gage seemed eager to set the case for a hearing. Because of an interest in allowing Ms. Dotson to present her evidence, she was permitted to add another expert.

Ms. Dotson submitted Dr. Shafrir's first report on December 20, 2021. Exhibit 84. Although this report is approximately 50 pages, the bulk (about 41 pages) summarize medical records through 2016. In the "discussion" section, Dr. Shafrir mainly addressed diagnosis. Dr. Shafrir opined that three potential diagnoses were ADEM, encephalitis, and vasculitis. Exhibit 84 at 43-44. Of these choices, Dr. Shafrir stated that vasculitis was the most likely. Dr. Shafrir generally agreed with Dr. Gershwin that the varicella vaccine was the most likely cause of the vasculitis, although Dr. Shafrir's opinion as to a potential causal connection between the varicella vaccine and the vasculitis was not particularly robust. See id. at 44-45. Dr. Shafrir also explained why acute viral encephalitis is not an appropriate diagnosis. Id. at 45-46. Dr. Shafrir critiqued some aspects of Dr. Kruer's opinion. However, Dr. Shafrir declined to address immunological parts of Dr. Kruer's second report because Dr. Shafrir anticipated that Dr. Gershwin would respond. Likewise, Dr. Shafrir did not discuss the radiology as addressed by Dr. Wilson and Dr. Zucconi.

Again, the Secretary responded with a pair of reports. Perhaps not surprisingly, given that Dr. Shafrir did not comment on the radiology, Dr. Zucconi maintained his opinion, which was that B.M. had acute viral encephalitis caused by a coronavirus. Exhibit AA.

Dr. Kruer's six-page report responded to Dr. Shafrir, nearly paragraph-by-paragraph. Dr. Kruer continued his opinions. Exhibit BB.

The parties discussed the completeness of the expert reports in a May 4, 2022 status conference. Ms. Dotson stated that for expert opinions, the parties have reached the bottom of the well. Thus, the next step was for the attorneys to organize the evidence through briefs. See Order, issued May 5, 2022. A July 28, 2022 order offered some guidance with respect to the expected content of the briefs. With respect to Althen prong one, which concerns a theory, Ms. Dotson was directed to "begin by summarizing the theory explaining how the varicella vaccine can cause cerebral vasculitis. The summary should not merely quote from the expert reports." Order, issued July 28, 2022, at 5. To the extent that she was attempting to demonstrate the soundness and reliability of any opinion causally connecting the varicella vaccine to vasculitis, the parties were directed to "include at least one paragraph about the article." Id. at 6.

Approximately only one week after the briefing order was issued, Ms. Dotson filed another report from Dr. Shafrir. Exhibit 99. This report was five pages and Dr. Shafrir cited eight articles.[14] Dr. Shafrir concludes: "Dr. Kruer's report contains no data to cause one to believe that BM suffered from coronaviruses OC43 encephalitis rather than CNS vasculitis." Id. at 5.

The Secretary objected to the submission of a report from Dr. Shafrir. Resp't's Status Rep., filed Aug. 15, 2022. A status conference was held on August 17, 2022. Ms. Dotson's defended the submission because she had a right to submit evidence. See Pet'r's Status Rep., filed Aug. 17, 2022. Furthermore, the July 28, 2022 briefing order specifically authorizes parties to file a reasonable number of medical articles when accompanied by a statement from an expert explaining them. In contrast, the Secretary maintained that the filing of an additional expert report after the briefing order issued frustrates the orderly presentation anticipated in the briefing order. The Secretary also argued that the submission of another expert report was inappropriate after Mr. Gage had represented in the May 4, 2022 status conference that the experts were done.

The Secretary's objection to Dr. Shafrir's August 3, 2022 report was overruled and this report remains in the record. The objection was overruled for two reasons: first, the July 28, 2022 order for briefs did allow for supplementation of expert reports and second, the Secretary would not be prejudiced. The Secretary could respond with more reports from Dr. Kruer and Dr. Zucconi.

[14] Dr. Shafrir, at times, criticizes Dr. Kreur with language that is potentially inflammatory and excessively personal. Dr. Shafrir is expected to express his opinions more respectfully and any counsel retaining Dr. Shafrir is also expected to monitor Dr. Shafrir's writing.

The Secretary did not file another report from Dr. Zucconi, probably because Dr. Shafrir's previous report did not really contest any opinions that Dr. Zucconi made about the imaging. However, the Secretary obtained another report from Dr. Kruer, which was filed on October 25, 2022. Attempting to refute Dr. Shafrir's criticisms, Dr. Kruer wrote approximately five more pages and cited five more articles. Exhibit CC.

E. Summary of Expert Reports

Dr. Kruer's report completed the submission of written reports from the experts. This process began with Dr. Gershwin's first report filed in April 2019.

The highlights of the expert reports are presented below:

#	Ex.	Party	Author	Summary
1	18	P1	Gershwin	Diagnosis = vasculitis. Challenge to immune deficiency and coronavirus infection.
2	40	P2	Gershwin	Althen prong 3.
3	47	P3	Gershwin	Copied much of prior two reports. Added some on theory / Althen prong 1.
4	C	R1	Kruer	Diagnosis: coronavirus infection in context of immunodeficiency.
5	P	R2	Kruer	Review of imaging. Some discussion of Althen prongs.
6	54	P4	Wilson	Review of imaging. Diagnosis = vasculopathy. Not coronavirus.
7	76	P5	Gershwin	One page, agreeing with Dr. Wilson.
8	V	R3	Zucconi	Review of imaging. Diagnosis = acute viral encephalitis.
9	X	R4	Kruer	Diagnosis = atypical coronavirus encephalitis. Brief discussion of Althen prongs.
10	77	P6	Gershwin	Diagnosis = VZV vasculopathy.

#	Ex.	Party	Author	Summary
11	Y	R5	Zucconi	Two pages about images supporting acute viral encephalitis.
12	Z	R6	Kruer	Disputing diagnosis of VZV vasculopathy.
13	84	P7	Shafrir	Detailed (40 pages) review of facts with commentary. Vasculitis is most likely diagnosis. Little or nothing about immunology and radiology.
14	AA	R7	Zucconi	Diagnosis: acute viral encephalitis caused by a coronavirus.
15	BB	R8	Kruer	Responding to Dr. Shafrir.
Briefing Order, filed July 28, 2022				
16	99	P8	Shafrir	Challenge to diagnosis of coronavirus encephalitis, rather than vasculitis.
17	CC	R9	Kruer	Responding to Dr. Shafrir.

F. Briefing Stage

After the parties finished disclosing the opinions from their experts, the next step was for the attorneys to marshal the evidence. Order, issued July 28, 2022. This process contained one wrinkle.

Ms. Dotson argued her case through a 40-page brief, filed Nov. 14, 2022. Ms. Dotson began by suggesting that a hearing regarding only diagnosis was appropriate. Although Ms. Dotson was "convinced" that the appropriate diagnosis for B.M. was vasculitis, the Secretary was contending that B.M. suffered from an encephalitis. Pet'r's Br. at 1. Ms. Dotson proposed that if the evidence were found to preponderate in favor of encephalitis as a diagnosis, then she "would present evidence dealing with vaccine caused encephalitis." Id. at 2.

This path was not contemplated in the July 28, 2022 briefing order. Thus, the Secretary was directed to respond only this aspect of Ms. Dotson's brief. Order, issued Nov. 22, 2022.

The Secretary objected to a plan in which entitlement could restart. Resp't's Status Rep., filed Dec. 2, 2022. During a December 22, 2022 status conference, Ms. Dotson withdrew her request for a hearing limited to diagnosis. However, she maintained her request for a hearing. Order, issued Dec. 22, 2022. Because the case was moving forward on all issues, the Secretary was directed to file his brief. Id.

The Secretary argued against a finding of entitlement in a 51-page brief, filed Jan. 31, 2023. The Secretary challenged (a) whether vasculitis was an appropriate diagnosis, (b) whether Ms. Dotson met her burden with respect to a theory, (c) whether Ms. Dotson met her burden with respect to a logical sequence of cause and effect, and (d) whether Ms. Dotson met her burden with respect to timing.

Ms. Dotson had what appeared to be the final word by filing a reply on March 2, 2023. This reply was approximately 10 pages.

Typically, the submission of a reply makes the case ready for adjudication. However, a preliminary review showed that Ms. Dotson had not articulated the theory (or theories) by which a varicella vaccine can cause vasculitis. See Order, issued Mar. 15, 2024. Thus, Ms. Dotson was directed to file a short memorandum. Id. The March 15, 2024 order also specified that "If petitioner is advancing more than one theory, petitioner shall separately number each theory." She was also instructed to tie up some loose ends, such as providing information about B.M.'s experience with the coronavirus circulating during the pandemic.

Ms. Dotson attempted to take care of these matters. She submitted a status report regarding theories. Pet'r's Mem., filed Apr. 3, 2024. She explained that B.M. has not tested positive for the current coronavirus. Exhibit 115 (affidavit).

The Secretary was permitted an opportunity to respond. Order, issued July 17, 2024 (also allowing Ms. Dotson to reply). The Secretary stated that he previously addressed the failure of Ms. Dotson's experts to present a cogent medical theory. Resp't's Status Rep., filed Aug. 7, 2024, citing Resp't's Br. at 41-45. The Secretary continued: "As to petitioner's status report, she did not number or name the theory or theories as instructed, and it is therefore not clear what respondent should be addressing." Id. The Secretary, nevertheless, made four points as to why Ms. Dotson had not satisfied Althen prong one.

Ms. Dotson was entitled to address these points through a reply brief. Order, issued July 12, 2024. However, she did not. The lack of reply leaves many points unrebutted. Regardless of the lack of reply, the case is ready for adjudication.

G. Adjudication without a Hearing

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018). Here, a hearing is not necessary to resolve Ms. Dotson's case. Ms. Dotson has submitted eight reports from experts and argued her case through briefs. She has had a full and fair opportunity to establish that she is entitled to compensation.

III. Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

Petitioners bear a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

IV. Analysis

Often, when the parties dispute the diagnosis, special masters resolve the question of diagnosis first. As the Federal Circuit has explained, in some circumstances, the special master may "first determine which injury was best supported by the evidence in the record before applying the Althen test." Broekelschen v. Sec'y of Health and Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). However, Ms. Dotson's case is unusual in that (a) B.M.'s diagnosis is a challenging question and (b) the case can be analyzed without resolving the question of diagnosis. As demonstrated below, even if B.M. were assumed to have vasculitis, Ms. Dotson's case still falters.

Ms. Dotson has failed to meet all the elements necessary to show that the varicella vaccine was the cause-in-fact of (an assumed) vasculitis. In most cases, the prong one inquiry is distinct from the prong two question. The former is about general causation, and the latter is about specific causation. Piscopo v. Sec'y of Health & Hum. Servs., 66 Fed. Cl. 49, 54 (2005). For Ms. Dotson, the separation is not so stark. Her attempts to present a creditable prong one theory were largely unsuccessful, negating the need for an extensive prong two analysis. To the extent that Ms. Dotson has presented a passable prong one theory, her case falls apart at prong two.

A. Althen Prong One - Theory

After multiple rounds of expert reports and rounds of briefing, whether Ms. Dotson has disclosed any theory is debatable. Ms. Dotson was notified repeatedly that the presentation of any theory was not adequate. She did largely not cure this deficiency. See Section IV.A.1. below.

To be fair, Ms. Dotson has not ignored her obligation to present a theory entirely. She has cited a handful of articles. This evidence is reviewed in Section IV.A.2, below.

An assessment of the evidence Ms. Dotson has advanced reveals that for the most part, the evidence falls short of meet her burden. Potentially, one theory may be viable. See Section IV.A.,3, below. But, that theory (a direct viral invasion) does not help Ms. Dotson establish that the varicella virus harmed B.M. See Section IV.B., below.

1. Opportunities to Disclose a Medical Theory

Represented by attorneys with experience in the Vaccine Program (Ms. Toale and Mr. Gage), Ms. Dotson knew that to prevail in this litigation she was required to present "a medical theory causally connecting the vaccination and the injury." Althen, 418 F.3d at 1278. This requirement was reinforced in final Instructions for experts, issued December 12, 2017.

Dr. Gershwin's first two attempts to put forward a minimally competent medical theory fell well short. After Dr. Gershwin wrote his May 14, 2019 report, the Secretary argued that the case should be dismissed. Resp't's Mot., filed May 29, 2019. Ms. Dotson did not attempt to defend the adequacy of this report. Instead, she added a second report. Any disclosure in the second report was also deficient as explained in the Second Order to Show Cause, issued Sep. 6, 2019. This Second Order to Show Cause explained that Ms. Dotson was unlikely to prevail if her expert advanced a theory based upon either a varicella infection or a hypersensitivity reaction. Id. at 3.

Dr. Gershwin's third report was sufficiently improved that the case could proceed. Dr. Gershwin appeared to have disclosed the theory of molecular mimicry. Exhibit 47 at 6, see also Order, issued Oct. 23, 2019 (memorializing discussions in a status conference in which Mr. Gage stated that Dr. Gershwin was advancing molecular mimicry).

However, this disclosure appeared not apparent to Dr. Kruer. In Dr. Kruer's second report, he asserted that Dr. Gershwin "has not proffered a theory of causality." Exhibit P at 3.

After Dr. Kruer's second report, the parties added more reports. However, these reports generally focused on diagnosis. See Section III.C., above (describing procedural history). Although Dr. Gershwin wrote more reports, Dr. Gershwin did not address Dr. Kruer's comment that he (Dr. Gershwin) did not disclose a theory. See Exhibit 76 (one page report from Dr. Gershwin agreeing with Dr. Wilson about diagnoses), Exhibit 77 (Dr. Gershwin maintaining the diagnosis of VZV vasculopathy).

Conceivably, Ms. Dotson's addition of Dr. Shafrir might have assisted her with meeting her burden for Althen prong one. See Thompson v. Sec'y of Health & Hum. Servs., No. 15-671V, 2023 WL 21234 (Fed. Cl. Spec. Mstr. Jan. 3, 2023); Quinones v. Sec'y of Health & Hum. Servs., No. 11-154V, 2019 WL 4745123 (Fed. Cl. Spec. Mstr. Sep. 4, 2019). However, Dr. Shafrir's first and lengthy report

also focused on diagnosis. Exhibit 84. At best, Dr. Shafrir discussed the potential causal association between the varicella vaccine and vasculitis in two paragraphs. Id. at 44. These two paragraphs do not meaningfully advance Ms. Dotson's evidence as Dr. Shafrir begins by stating "As indicated by Dr. Gershwin . . ." Id. Dr. Shafrir cites two articles, which Dr. Gershwin had already cited. Two pages later, Dr. Shafrir essentially repeats these two paragraphs. Id. at 46. This was the last expert report to comment upon a prong one theory as Dr. Shafrir's second report again was about diagnosis. See Exhibit 99.

When the parties were instructed to brief the issues, Ms. Dotson was reminded to set forth the theory or theories on which she was asserting. Order, issued July 28, 2022. Both parties were directed to identify the articles that supported or detracted from the soundness of any medical theory. Id. at 6.

In Ms. Dotson's brief, she discussed Althen prong one in approximately two double-spaced pages. Pet'r's Br. at 36-38. This section begins "There is abundant evidence linking varicella to vasculitis. The literature treats it as a given." Id. at 36. She did not identify any theory. For example, although Mr. Gage had represented in the October 23, 2019 status conference that Dr. Gershwin was asserting molecular mimicry, the term "mimic" does not appear in this brief. Ms. Dotson did, however, write a paragraph or two paragraphs about four articles---Gilden (Exhibit 51),[15] Nagel (Exhibit 33),[16] Strauss (Exhibit 46),[17] and Agger (Exhibit 95).[18]

In response, the Secretary generally argued that these four articles did not support Ms. Dotson's claim. Resp't's Br. at 42-43. In doing so, the Secretary commented that as "Dr. Kruer has noted, petitioner has not offered any cogent theory of causation." Id. at 43, citing, among other items, Exhibit P at 3.

---

[15] Don Gilden et al., Varicella zoster virus vasculopathies: diverse clinical manifestations, laboratory features, pathogenesis, and treatment, 8 LANCET NEUROL. (2009); filed as Exhibit 51.

[16] Maria A. Nagel & Don Gilden, Developments in Varicella Zoster Virus Vasculopathy, 16 CURR. NUEROL. NUEROSCI. REP. (2016); filed as Exhibit 33.

[17] Stephen E. Straus, Varicella-Zoster Virus Infections, 108 ANNALS OF INTERNAL MEDICINE 221 (1988); filed as Exhibit 46.

[18] William A. Agger et al., Increased Incidence of Giant Cell Arteritis After Introduction of a Live Varicella Zoster Virus Vaccine, OPEN FORUM INFECTIOUS DISEASES (2020); filed as Exhibit 95.

Ms. Dotson seems to have attempted to address this point. She block-quoted a portion of Dr. Gershwin's third report, which contains the term "molecular mimicry." Pet'r's Reply at 2. (The lengthy quotation is inconsistent with the July 28, 2022 briefing order, which directed the parties not to quote from the expert's reports). In this context, Ms. Dotson did not discuss any additional articles. (The block quote actually eliminated references within Dr. Gershwin's report).

To ascertain whether Ms. Dotson had presented any medical theory, an order was issued for clarification from Ms. Dotson. Order, issued March 24, 2024. Ms. Dotson was instructed to specify the theories on which she was relying.

Ms. Dotson repeated a block quote from Dr. Gershwin's second report and, this time, included two references, references 5 and 6. Pet'r's Status Rep., filed Apr. 3, 2024, at 1. For sake of completeness, Ms. Dotson's argument is reproduced in full:

> "It should be emphasized that vasculitis are a very heterogeneous group of rare diseases that are typically classified based on the size of the blood vessel involved and the anatomic location. In all cases, there is significant inflammation, which is driven by mononuclear cells and/or immune complex-mediated inflammatory processes. The occurrence herein within 4 weeks would be consistent with either mechanism, i.e. either the production of mononuclear cells specific for vascular antigens, the presence of crossreactive antibodies, i.e. molecular mimicry, and /or antibody-[dependent] cells-mediated cytotoxicity (5,6)."

Pet'r's Status Rep., filed Apr. 3, 2024, at 1, quoting Exhibit 40 (Dr. Gershwin's June 18, 2019 report) at 1. Reference 6 is an article by Guillevin (Exhibit 41).[19] Ms. Dotson did not elaborate on any argument based upon reference 5, which is an article by Rojas and filed as Exhibit 45.[20] Ms. Dotson's status report also includes

[19] Loic Guillevin & Thomas Dörner, Vasculitis: mechanisms involved and clinical manifestations, 9 ARTHRITIS RESEARCH & THERAPY (2007); filed as Exhibit 41.

[20] Manuel Rojas et al., Molecular mimicry and autoimmunity, 95 J. OF AUTOIMMUNITY 100 (2018); filed as Exhibit 45.

a block quote from Twilt (Exhibit 87).[21] Ms. Dotson included about one sentence from three other articles: Cellucci & Benseler (Exhibit 98), Nagel & Gilden (Exhibit 33) and Wise (Exhibit 37).[22] Finally, without any descriptive information, she cited eight other articles. She wrote: "Also see Exhibits 34, 35, 50, 71, 72, 73, 78 and 87." Pet'r's Status Rep., filed Apr. 3, 2024, at 1.[23]

---

[21] Marinka Twilt & Susanne M. Benseler, CNS vasculitis in children, 2 MULTIPLE SCLEROSIS AND RELATED DISORDERS 162 (2012); filed as Exhibit 87.

[22] Robert P. Wise et al., Postlicensure Safety Surveillance for Varicella Vaccine, 284 J. OF THE AM. MED. ASS'N 1271 (2000); filed as Exhibit 37.

[23] In other briefs, Ms. Dotson slightly developed arguments based upon two articles, which are Exhibit 34 (Nagel and Bubak) and Exhibit 87 (Twilt and Benesler). These two articles are consequently discussed below.

For the remaining articles in this string cite, Ms. Dotson's citation to the articles without any explanation of their relevance could justify striking the articles. See Sheller v. Sec'y of Health & Hum. Servs., 121 F.4th 1301, 1309 (Fed. Cir. 2024); Order for Briefs, issued July 28, 2022, at 6 ("for every article that the party finds relevant, the brief will include at least one paragraph about the article. . . . Conversely, the omission of an article from the brief is likely to be interpreted as an indication that the article is not important. Unimportant articles are subject to being struck from the record").

Nevertheless, out of an abundance of caution, the undersigned has reviewed these articles. In absence of any advocacy from Ms. Dotson, the undersigned recognizes that three of the six remaining articles appear to discuss how a varicella infection is associated with a vasculitis. These are Exhibit 50 (Isabella Uhoda, Varicella-Zoster Virus Vasculitis: A Case of Recurrent Varicella without Epidermal Involvement, 200 DERMATOLOGY 173 (2000)); Exhibit 72 (Maria A. Nagel and Don Gilden, Developments in Varicella Zoster Virus Encephalopathy, 16(12) CURR NEUROL NEUROSCI REP 11 (2016)); Exhibit 78 (Don Gilden et al., Varicella zoster virus vasculopathies: diverse clinical manifestations, laboratory features, pathogenesis, and treatment, 8(8) LANCET NEUROL. 731 (2009)). These three articles, which have some overlaps in authorships, largely repeat information presented in other articles discussed in the text.

At least two of the cited, but undiscussed, articles focus on conditions not at issue in Ms. Dotson's case. See Exhibit 71 (Elaine Wirrell, Stroke after Varicella Vaccination, 145 J. PEDIATRICS 845 (2004)) and Exhibit 73 (Til Menge, Acute Disseminated Encephalomyelitis, 62 ARCH NEUROL 1673 (2005)). Ms. Dotson has not persuasively explained why B.M.'s asserted condition is analogous to either stroke or acute disseminated encephalomyelitis.

The final cited, but undiscussed, article, is a case report concerning a different vaccine. Exhibit 35 (Vikram Puram et al., A Unique Case Report on Hypersensitivity Vasculitis as an Allergic Reaction to the Herpes Zoster Vaccine, 53(1) VASCULAR AND ENDOVASCULAR SURGERY 78 (2019)). In general, case reports provide little, if any, information helpful to determining causation because they present only a temporal sequence of events in which the

The Secretary maintained that Ms. Dotson's experts have "fail[ed] to put forward a cogent medical theory that causally connects the varicella vaccine to vasculitis." Resp't's Status Rep., filed Aug. 7, 2024, at 2. The Secretary also pointed out that Ms. Dotson did not comply with the requirement in the March 15, 2024 order that she separately number the theories she was asserting.

Ms. Dotson had one final chance to identify the theories she was asserting by filing a reply brief. See Order, issued July 12, 2024. However, she was silent.

Given these opportunities, Ms. Dotson's lack of clarity about the theory (or theories) is detrimental to her case. Presenting a sound and reliable theory is essential to Ms. Dotson's case. A theory causally connecting the vaccine to the injury is the first Althen prong. When petitioners fail to establish this element, compensation is denied. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1360-62 (Fed. Cir. 2019). Moreover, the theory advanced for Althen prong one influences the remaining two Althen prongs. For the second Althen prong, which addresses whether a logical sequence connects the vaccine to the injury, special masters may consider whether the vaccinee responded in a way consistent with the theory being offered. Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1364 (Fed. Cir. 2012); Miller v. Sec'y of Health & Hum. Servs., 172 Fed. Cl. 762, 784 (2024) (finding special master did not err in denying entitlement when petitioner did not establish that she had immune complexes after asserting a theory involving immune complexes); Dodd v. Sec'y of Health & Hum. Servs., 114 Fed. Cl. 43, 52-57 (2013); La Londe v. Sec'y of Health & Hum. Servs., 110 Fed. Cl. 184, 205 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). Similarly, the third Althen prong, which concerns timing, depends, at least in part, upon the theory being offered. Langland v. Sec'y of Health & Hum. Servs., 109 Fed. Cl. 421, 443 (2013); see also Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1244-45 (Fed. Cir. 2014) (holding that special master was not arbitrary in finding an onset of injury seven months after vaccination was incompatible with a theory based upon cytokines). Without a defined theory, attempting to determine whether preponderant evidence supports the logical sequence or timing is difficult or impossible.

Consistent with an obligation to resolve cases based upon the entire record (42 U.S.C. § 300aa–13(a)), the undersigned has attempted to discern the theory (or

---

vaccination preceded an adverse health event. See K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports).

theories) that Ms. Dotson is advancing. The undersigned took the unusual step of giving Ms. Dotson and her attorney, Mr. Gage, a second opportunity to clarify her theory by issuing the March 15, 2024 order.

In response to the direct question contained in the March 15, 2024 order (what is petitioner's theory or theories?), Ms. Dotson should have provided a direct answer. She did not. This vagueness does not help her case. Judicial officers "are not like pigs hunting for truffles buried in briefs." Parus Holdings, Inc. v. Google, L.L.C., 70 F.4th 1365, 1371-72 (Fed. Cir. 2023); Pipes v. United States, 123 F.4th 1324, 1331 (Fed. Cir. 2024); accord Wheless v. United States, 173 Fed. Cl. 215, 227 (2024) ("The Court cautions parties against throwing half-baked arguments against the wall to see if the Court will do the work to make them stick").

2. Articles Ms. Dotson Has Discussed

As extensively discussed above, Ms. Dotson's presentations made in reports from her experts and in briefs are far from a model of clarity. Nevertheless, she has advanced some articles.

a) Wise and Epidemiological Studies

A primary piece of evidence is the article by Wise.[24] Dr. Gershwin cited that article in his first report and his third report. See Exhibit 18 at 5 (reference 13), Exhibit 47 at 5 (exhibit 37). Ms. Dotson did not cite this article in her brief or her reply. However, in the April 3, 2024 status report, she asserted that the authors reported cases of vasculitis after a varicella vaccine.

In this article, Robert P. Wise and colleagues searched Vaccine Adverse Event Reporting System (VAERS). "VAERS data are typical of passive drug safety surveillance programs." Exhibit 37 at 1272. For reports filed between March 17, 1995 through July 25, 1998, the researchers searched for diseases that were reported to develop after a varicella vaccine. Id. They found 15 cases of vasculitis. Id. at 1273 (Table 2). "Among 15 vasculitis reports, 3 children aged 1 to 3 years appeared to have Kawasaki syndrome, and 10 patients developed Henoch-Schönlein purpura within 7 weeks of vaccination." Id. at 1275. The authors recognized several "inherent limitations" of VAERS data. Id. at 1276.

[24] Although Ms. Dotson characterizes Wise as an epidemiological study, Wise did not contain any controls. Thus, whether Wise is a "study" of any type is questionable.

They proposed additional research, including projects involving the Vaccine Safety Datalink Project. Id. at 1278.[25]

The Secretary's expert, Dr. Kruer, criticized this article for its "major confounding factors and the lack of a control group." Exhibit BB at 2. Dr. Kruer cited a different study by Di Pietrantonj.

The Di Pietrantonj article is relatively long, exceeding more than 400 pages, according to its Table of Contents. (The Secretary excerpted 86 pages in Exhibit BB, tab 2.)[26] A review of this article did not readily identify any places in which the authors assessed whether the varicella vaccine can cause vasculitis.[27] Thus, from one perspective, Dr. Kruer is correct in asserting that "no evidence linking varicella vaccine . . . to vasculitis was identified." Exhibit BB at 2. However, the "no evidence" could reflect a lack of studies investigating this possibility. Therefore, this Di Pietrantonj article does not undermine the claim that a varicella vaccine can cause vasculitis.[28]

The relative weakness of the Di Pietrantonj article does not elevate the value of the Wise article. Wise's methodology of extracting data from the VAERS database is not reliable. See H.L. v. Sec'y of Health & Hum. Servs., 715 Fed. App'x 990, 995-96 (Fed. Cir. 2017); Analla v. Sec'y of Health & Hum. Servs., 70 Fed. Cl. 552, 558 (2006).

Through Dr. Shafrir, Ms. Dotson advanced an epidemiologic study in which researchers investigated whether a live attenuated herpes zoster vaccine (ZVL) affected the incidence of giant cell arteritis. Exhibit 95 (Agger); see also Exhibit 84 (Dr. Shafrir's report) at 45; Pet'r's Br. at 37. Giant cell arteritis "causes inflammation in the walls of medium and large elastic arteries of the head."

---

[25] In a different case, Dr. Wise testified that his purpose in writing this article was to summarize adverse events. Casey v. Sec'y of Health & Hum. Servs., No. 97-612V, 2005 WL 3597263, at *14 (Fed. Cl. Spec. Mstr. Dec. 12, 2005).

[26] Carlo Di Petrantonj et al., Vaccines for measles, mumps, rubella, and varicella in children, 11 COCHRANE DATABASE SYST. REV. (2021); filed as Exhibit BB, tab 2.

[27] The authors had "low" certainty about a finding that the mumps-measles-rubella vaccine could cause Henoch-Schönlein purpura. Exhibit BB, tab 2 at 21 (finding 14), 56. However, Ms. Dotson has not claimed that the MMR portion of the Pro-Quad vaccine that her son received harmed him.

[28] By way of contrast, studies investigated whether MMR vaccines are associated with autism and did not find a link. See Exhibit BB, tab 2 at 21 (finding 9).

Exhibit 95 at 1. People who suffer from giant cell arteritis are usually older than 50 years. Id. at 2 (discussing diagnostic criteria). All the people in this study were at least 60 years old. Id. (discussing population). The researchers found that the "ZVL vaccination was associated with an increased risk of GCA diagnosis." Id. at 3. The authors explained that the "association may potentially be attributed to (1) subacute or persistent arterial wall infection with ZVL, (2) a ZVL vaccine-driven cellular immune response to VZV already present in the arterial walls, or (3) a non-viral specific autoimmune reaction triggered by ZVL." Id. at 4.

Dr. Kruer distinguished the Agger study on giant cell arteritis because giant cell arteritis "is essentially unheard of in children." Exhibit CC at 3. Thus, in Dr. Kruer's view, the Agger study holds "doubtful relevance to this case as BM was a small child at the time his injury occurred." Id.

Although an affirmative epidemiological study could have helped Ms. Dotson establish that the varicella vaccine can cause vasculitis, the Wise study is not persuasive evidence for this proposition. See Stapleford v. Sec'y of Health & Hum. Servs., No. 03-234V, 2009 WL 1456441, at *8 (Fed. Cl. Spec. Mstr. May 1, 2009) (finding that petitioner did not establish that a varicella vaccine caused a seizure disorder and discussing Wise). But the lack of an epidemiological study does not doom the claim because a petitioner is not required to present an epidemiologic study. Althen, 418 F.3d at 1280.

b) Nagel and Gilden / Exhibit 33

Dr. Gershwin cited this article as reference 15 in his first report. Exhibit 18 at 5. After Ms. Dotson filed it as exhibit 33, Dr. Gershwin again cited it in his third report. Exhibit 47 at 5. Ms. Dotson cited this article. Pet'r's Br. at 36-37; Pet'r's Status Rep. at 3.

In this article, the co-authors focused on the association of varicella zoster virus and stroke. A stroke is due to "productive VZV infection of cerebral arteries." Exhibit 33 (Nagel and Gilden) at 1.[29] The authors elaborated that "VZV, a highly neurotrophic member of the herpes family, is the only human virus that has been shown to replicate in arteries and produce disease." Id. at 2. Under pathogenesis, the article states: "After reactivation from cranial nerve ganglia, VZV likely spreads transaxonally to the outermost adventitial layer of the artery wall; infected cerebral arteries contain a thickened intima composed of

[29] Ms. Dotson submitted a manuscript version, not a copy of the article as it appears in publication.

myofibroblasts, a disrupted internal elastic lamina, and a paucity of smooth muscle cells." Id. at 3.

The Nagel and Gilden article also discussed varicella vaccines and vasculopathy. The article distinguished between the Zostavax vaccine, which is given to adults to prevent shingles, and Varivax, which is given to children. The authors cited one report in which two children developed ischemic strokes 5 days and 3 weeks after a varicella immunization. Id. at 4. In a third case, an immunocompromised child developed multifocal large artery vasculopathy after a varicella vaccine. Id.

c) Strauss / Exhibit 46

Dr. Gershwin cited this article in his second report (Exhibit 40 at 2 (reference 1)) and in his third report (Exhibit 47 at 7). Ms. Dotson cited this article. Pet'r's Br. at 37.

This article reported a complication of a zoster infection was cerebrovasculopathy. Exhibit 46 at 228. The references supporting this assertion are from 1983 and 1986.

With respect to live varicella vaccines, the article reported some side effects. However, vasculitis does not appear among them. Exhibit 46 at 233-34.

d) Gilden / Exhibit 51

Dr. Gershwin cited this article in his third report as supporting an asserting that "vascular lesions produced by Varicella are reflective of a productive viral infection in cerebral arteries." Exhibit 47 at 7. Gilden corroborates this assertion as the article states "VZV vasculopathy is caused by productive viral infection in arteries." Exhibit 51 at 8.[30]

e) Nagel and Bubank / Exhibit 34[31]

Dr. Gershwin cited this article (reference 12) in his first report in support of a statement that in 13 cases, children who received varicella vaccine were reported to develop vasculitis. Exhibit 18 at 5. In his third report, Dr. Gershwin again cited

[30] Ms. Dotson filed a manuscript version of this article.

[31] Maria A. Nagel & Andrew N. Bubak, Varicella Zoster Virus Vasculopathy, 218 J. OF INFECTIOUS DISEASES 107 (2018); filed as Exhibit 34. This article was also filed as Exhibit 57.

this report. Exhibit 47 at 7. Ms. Dotson cites this article only twice in her brief. The information in this article resembles the information presented in Nagel and Gilden article.

f) Rojas / Exhibit 45 & Guillevin / Exhibit 41

In the context of Althen prong three, Dr. Gershwin cited these two articles as references 5 and 6, respectively. Exhibit 40 at 1. Dr. Gershwin wrote that the development of vasculitis within four weeks of the vaccination "would be consistent with either mechanism, i.e. either the production of mononuclear cells specific for vascular antigens, the presence of cross-reactive antibody, i.e. molecular mimicry, and/or antibody-dependent cell-mediated cytotoxicity." Id.

When called upon to present a comprehensive opinion, Dr. Gershwin slightly revised this portion. Again, Dr. Gershwin cited these articles in the context of Althen prong three. He wrote: "The mechanism herein is similar to other causes of vasculitis. . . . priming and generation of mononuclear cells that cross react with Varicella antigens found in blood vessels." Exhibit 47 at 6 (ellipses in Dr. Gershwin's report). This reference to "cross react" is consistent with molecular mimicry, which was mentioned in the second report.

These articles are absent from Ms. Dotson's primary brief. However, the March 1, 2023 reply block-quoted from Dr. Gershwin's third report, including the passage about "cross react." Pet'r's Reply at 2. However, Ms. Dotson otherwise did not expand upon what theory or theories the Rojas article and the Guillevin article supported. Ms. Dotson's April 3, 2024 status report quotes one sentence from the Guillevin article and does not discuss the Rojas article.

Rojas article has limited usefulness in providing a theory to explain how varicella vaccine can cause vasculitis in Ms. Dotson's case. Manuel Rojas and colleagues (including Dr. Gershwin) discussed how infections may induce autoimmune diseases through molecular mimicry. Exhibit 45. They detail evidence in approximately a dozen diseases, but none are vasculitis. See id. at 4-9.

The other article Dr. Gershwin in this context is by Loic Guillevin and Thomas Dörner. Ms. Dotson quoted, accurately, a passage from the abstract: "Various pathogenic mechanisms have been implicated in the induction of vasculitis, including cell-mediated inflammation, immune complex-mediated inflammation and autoantibody-mediated inflammation." Exhibit 41 at 1. The authors provided examples of each potential pathogenesis: cell-mediated inflammation is for giant cell arteritis, immune complex-mediated inflammation is

for Henoch-Schönlein purpura, and autoantibodies for necrotizing glomerulonephritis. Id. at 2. This division suggests that different diseases have different pathologic pathways. Guillevin and Dörner did not discuss varicella as an inciting agent.

g) Celluci and Benesler / Exhibit 98 & Twilt and Beneseler / Exhibit 87

The discussion of potential pathologic mechanisms in Guillevin and Dörner resembles, in some respects, two other articles Ms. Dotson put forward: an article by Tania Cellucci and Sussane M. Benseler (Exhibit 98) and an article by Marinka Twilt and Susanne M. Benseler (Exhibit 87). See Pet'r's Status Rep., April 3, 2024, at 2-3. Dr. Shafrir cited Cellucci and Benseler as well as Twilt and Benseler to support his opinion that a person can be suffering from vasculitis in the central nervous system even if an angiography is negative. Exhibit 84 at 45, 48. In other words, Dr. Shafrir was relying upon these articles for diagnosis, not a theory. Nonetheless, Ms. Dotson quoted the Cellucci and Benseler article as saying "CNS vasculitis secondary to infection may result from direct pathogen invasion of the vessels or may be due to an immune-mediated response provoked by molecular mimicry, immune complex deposition, secretion of cytokines, and/or superantigen-mediated responses." Exhibit 98 at 733. The Twilt and Benseler article, in turn, also discussed different methods by which vasculitis might develop:

> Activated immune cells, such as T- and B-cells, and macrophages can cause an inflammatory response with production of cytokines and antibodies which can target different brain structures such as specific segments of blood vessels, neurons, or CNS proteins such as myelin, cell surface receptors, channels or enzymes. Inflammatory pathways can then be activated and cause characteristic clinical, radiographic and histological findings.

Exhibit 87 at 163. In the preceding sentence, the authors stated that "Inflammatory brain diseases represent a spectrum of illnesses that can occur in the context of an underlying focal or systemic condition (secondary Inflammatory brain diseases) such as an infection." Id.

This concludes the set of articles about which Ms. Dotson wrote at least one sentence in the context of Althen prong one.

3. Assessment

As noted earlier, neither the Wise article nor the Agger study carry Ms. Dotson's burden to demonstrate that the varicella vaccine can cause vasculitis. The analysis of that evidence will not be repeated in this section. Instead, this section focuses upon the theories that potentially have been advanced. They are organized into two categories: first, a bucket of other theories and second, the direct viral invasion theory.

a) Miscellaneous Theories

Except for a theory based upon direct viral invasion, which is discussed below, any other theories were presented in such an abbreviated form that they are not sound and reliable. Examples include molecular mimicry, immune complexes, and cytokines.

Molecular Mimicry. Molecular mimicry often appears as a theory in Vaccine Program cases See Hoffman v. Sec'y of Health & Hum. Servs., No. 19-111V, 2024 WL 4444773 (Fed. Cl. Spec. Mstr. Sept. 13, 2024) (appendix listing cases). The Rojas article demonstrates that some people in the medical community propose molecular mimicry as a theory to explain how some autoimmune diseases develop. Exhibit 45.

It is also the case that Dr. Gershwin's reports at least mention the idea. His second report includes the phrase "the presence of cross-reactivity antibody, i.e. molecular mimicry" in the context of Althen prong three. Exhibit 40 at 1. Likewise, Dr. Gershwin's third report uses the phrase "cross react with Varicella antigens." Exhibit 47 at 6. This phrase was included as part of a block quote when Ms. Dotson was advocating. Pet'r's Reply at 2.

Ms. Dotson's evidence and arguments regarding molecular mimicry are too general to be persuasive. Special masters are not arbitrary in refraining from crediting an opinion based upon molecular mimicry when the petitioner's expert "never actually explains how molecular mimicry might occur from the [relevant] vaccine specifically." Dennington v. Sec'y of Health & Hum. Servcs., 167 Fed. Cl. 640, 653 (2023), app dismissed, No. 24-1214, 2024 WL 1255318 (Fed. Cir. 2024).

Immune Complexes. Like molecular mimicry, the theory of immune complexes has appeared in Vaccine Program cases. E.g. Miller, 172 Fed. Cl. at 784 (denying motion for review when petitioner did not establish that she suffered from immune complexes). However, the evidence about immune complexes as a way to explain how a varicella vaccine can cause vasculitis in this case is meager.

To start, Dr. Gershwin wrote about "immune complexes" in one sentence of his second report and repeated this sentence in his third report. See Exhibits 40 at 1 and Exhibit 47 at 6. Otherwise, he did not elaborate. The theory of immune complexes is mentioned in at least two articles. The Celluci & Benseler article mentions "immune complex deposition" as one of several methods by which CNS vasculitis might originate. Exhibit 98 at 733. However, this article does not propose that any immune complexes would involve a vaccine.

The other article proposing immune complexes as a way to explain some forms of vasculitis is by Guillevin and Dorner. Exhibit 41 at 1. These authors state that inflammation mediated by immune complexes causes Henoch-Schönlein purpura. Exhibit 41 at 2. However, again, the authors do not link the creation of immune complexes with vaccines. Moreover, Ms. Dotson has not presented persuasive evidence that Henoch-Schönlein purpura is analogous to CNS vasculitis.

Cytokines. A third theory that arguably is in play involves cytokines. However, the source of information about cytokines in this case is not Dr. Gershwin. None of his three reports use the term cytokines. See Exhibits 18, 40, and 47. Because petitioners must rely upon medical records or medical opinions (42 U.S.C. § 300aa–13(a)), the lack of disclosure from Dr. Gershwin appears to prevent Ms. Dotson from prevailing on this theory. See Vaccine Rule 8(f)(1). Rather, the term "cytokines" appears in two articles, which Dr. Shafrir cited regarding diagnosis. See Exhibit 98 (Cellucci and Benseler) at 733, Exhibit 87 (Twilt and Benseler) at 163.

Evaluation. These theories lack sufficient development. One sentence or two sentences do not establish the soundness of any of them.

The Court of Federal Claims has ruled that special masters are not arbitrary when they reject unsubstantiated theories. Examples include: Temes v. Sec'y of Health & Hum. Servs., 151 Fed. Cl. 448, 461 (2020) ("Dr. Bellanti did not provide any support—by way of medical literature or otherwise—for his opinion that either molecular mimicry or bystander activation played a role"); Shapiro v. Sec'y of Health & Hum. Servs., 105 Fed. Cl. 353, 359 (2012) (agreeing with special master's assessment that petitioner's expert's presentation of some theories was "extremely cursory"), aff'd without op., 403 Fed. App'x 952 (2013); see also Baron v. Sec'y of Health & Human Servs., No. 14-341V, 2019 WL 2273484, at *17 (Fed. Cl. Spec. Mstr. Mar. 18, 2019) (petitioners "need to propose something more than taking a vague 'kitchen sink' approach and listing eleven mechanisms that have been previously submitted in the Program for claims of vaccine-caused

injury with various degrees of success. Petitioners have listed many possibilities but have not identified a sound and reliable explanation that can be applied to the vaccines and injury in this case").

Accordingly, molecular mimicry, immune complexes, and cytokines are found to be inadequate under Althen prong one due to the lack of evidence supporting their reliability as a means to explain how the varicella vaccine can cause vasculitis.

b) Direct Viral Invasion

According to some articles, a varicella infection may lead to complications because the infection is "productive." Exhibit 33 (Nagel & Gilden) at 1. Because the varicella vaccine contains a live, but attenuated, virus, a theory that the varicella vaccine can cause an injury that the virus itself can cause seems to possess some minimal amount of soundness and reliability.

A greater amount of disclosure from Ms. Dotson's experts could have enhanced the value of the theory. Nevertheless, if only for the sake of advancing the analysis, it is assumed that (a) Ms. Doston intended to advance "viral infection" as a theory to explain how the varicella vaccine can cause vasculitis and (b) this theory satisfies the first prong of Althen. See Astle v. Sec'y of Health & Hum. Servs., No. 14-369V, 2018 WL 2682974, at *21 (Fed. Cl. Spec. Mstr. May 15, 2018) (stating that the varicella virus "is known to infect nerves and blood vessels in the brain").[32]

B. Althen Prong Two

As alluded to earlier, presenting an adequate theory under Althen prong one is an essential prerequisite to assessing whether a petitioner has met the burden with respect to a logical sequence of cause and effect. "The causal theory accepted under the first prong determines which theory of causation the special master must consider under the second prong." Quintana v. Sec'y of Health & Hum. Servs., No. 15-1273V, 2022 WL 1873849, at *10 (Fed. Cl. 2022); accord Miller, 172 Fed. Cl. at 775.

[32] Although the parties were directed to cite reasoned opinions from special masters about the causal theory proposed, Order, issued July 28, 2022, at 7, Ms. Dotson did not cite Astle or any other case supporting her theory.

As explained at length above, the theory with the most robust support---and the only theory advanced with any meaningful corroboration---is the theory that the varicella virus from the vaccine infects a person to cause CNS vasculitis.[33]

Regardless of the strength of this theory as an abstract proposition, the theory of a direct viral invasion does not help Ms. Dotson show that the varicella vaccine caused her son's vasculitis. The Second Order to Show Cause, issued September 6, 2019, tentatively found that Ms. Dotson could not be found entitled to compensation based upon the theory of a direct invasion. Strong evidence against the usefulness of this theory in the context of B.M. came from Dr. Gershwin, who wrote: "I submit that there is no evidence of infection." Exhibit 18 at 4. Ms. Dotson agreed. See Pet'r's Resp. to Second Order to Show Cause, filed June 12, 2019, at 5 ("Dr. Gershwin points out that the medical records record no symptoms of infection"). The Secretary, too, stated that B.M. did not have a varicella infection: B.M.'s "clinical symptoms and findings were not consistent with a varicella-mediated disease. B.M. did not have symptoms or findings of a varicella skin disease, as he had no varicella type of rash, which would be a requirement for a disseminated varicella vaccine-strain disease. B.M.'s [cerebrospinal fluid] [varicella zoster virus] [polymerase chain reaction] was negative." Resp't's Rep. at 10-11. The disconnect between what the theory proposes---a viral infection with varicella---and what actually happened to B.M.---a lack of preponderant evidence showing a varicella infection---means that Ms. Dotson cannot prevail on prong two. For examples of appellate authorities ruling that special masters were not arbitrary in finding that a vaccinee did not respond as the theory predicted, see Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1364 (Fed. Cir. 2012) (when petitioner's theory was based upon the vaccine causing an autonomic neuropathy, "it was plainly necessary" for petitioner to establish she suffered from an autonomic neuropathy); Miller v. Sec'y of Health & Hum. Servs., 172 Fed. Cl. 762, 784 (2024) (when asserted a theory involving immune complexes, petitioner was required to show that she had immune complexes); Dodd v. Sec'y of Health & Hum. Servs., 114 Fed. Cl. 43, 52-57 (2013) (when petitioner hypothesized a lowering of seizure threshold, special master could find that the evidence did not support such a lowering); La Londe v. Sec'y of Health & Hum. Servs., 110 Fed. Cl. 184, 202-05 (2013) (petitioner's

[33] The phrasing "with the most support" should not be interpreted as implying that Ms. Dotson presented preponderant support for a theory based upon a direct viral infection. Instead, Ms. Dotson presented negligible support for the other theories, such as molecular mimicry. It is largely due to the deficiencies on these other theories that the direct viral invasion has risen to the top.

theory was premised on a loss of oxygen but evidence did not show an ongoing loss of oxygen), aff'd, 746 F.3d 1334 (Fed. Cir. 2014); Ricci v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 385, 391 (2011) (petitioner's theory predicted inflammation but no evidence showed child-vaccinee suffered inflammation); see also Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1362-63 (Fed. Cir. 2019) (when petitioner's claim is premised upon a child-vaccinee having a brainstem abnormality, petitioner must present proof that child-vaccinee had such abnormality).

The foregoing presupposes that B.M. suffered from vasculitis, which is the condition proposed by Ms. Dotson and her experts. However, the Secretary contends the more fitting diagnoses is an encephalitis caused by an infection with a coronavirus. Resolving this challenging question is unnecessary because even assuming that Ms. Dotson's suggested diagnosis were established preponderantly, the remainder of Ms. Dotson's case lacks coherence.

C. Althen Prong Three

The timing prong actually contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013). Here, the parties dispute the "medically acceptable" time.

The parties do not dispute the onset of B.M.'s disease. They agree that B.M.'s illness started with a fever on December 1, 2014, which is 21 days after the vaccination. See Resp't's Br. at 50 n.13. This agreement about onset leaves the question about the appropriate interval.

As with prong two, any analysis of the first part of Althen prong three requires an acceptance of a theory under prong one. Langland., 109 Fed. Cl. at 443. The theory is linked to the expected temporal interval because different theories might take different amounts of time. For example, a theory driven by cytokines is likely to take no more than a few days because cytokines develop and fade quickly after a vaccination. See Gram v. Sec'y of Health & Hum. Servs., No. 15-515V, 2022 WL 17687972, at *31, *51 (Fed. Cl. Spec. Mstr. Nov. 16, 2022) (finding more than 15 days too long for a theory that the MMR vaccine caused afebrile seizures).

Ms. Dotson's best theory, again, is a theory that the virus from the varicella vaccine infected B.M. and caused him to suffer vasculitis. If one were to set aside the dispositive fact that B.M. was not found to be infected with the varicella virus, then the direct viral invasion theory could work for Ms. Dotson with respect to prong three. A varicella infection preceded an ischemic stroke by three weeks in one report. Exhibit 33 (Nagel & Gilden) at 4. This evidence appears to be sufficient to find that Ms. Dotson might have prevailed upon Althen prong three.

A more detailed assessment is not required because Ms. Dotson's claim falters on Althen prong two. Even if the timing were appropriate, she would not necessarily be entitled to compensation. Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("Temporal association is not sufficient, however, to establish causation in fact.").

D. Elements of Respondent's Case

The analysis began with an assumption that Ms. Dotson had presented preponderant proof that B.M. suffered from vasculitis. This assumption was made because from one perspective, the question of diagnosis does not determine the outcome of Ms. Dotson's claim. As the analysis shows, Ms. Dotson did not present a theory (or theories) to explain how a varicella vaccine can cause CNS vasculitis very well. The only potentially viable theory is that the attenuated but live virus infected B.M. But, this theory does not match what actually happened to B.M. because he was not shown to have suffered a varicella infection. For these reasons, Ms. Dotson did not meet her burden of proof and the Secretary is not obligated to present an alternative cause. See LaLonde v. Sec'y of Health & Hum. Servs., 746 F.3d 1334, 1340 (Fed. Cir. 2014).

It bears repeating that one of the Secretary's primary arguments is that B.M. suffered from an encephalitis due to an infection with the coronavirus. See Resp't's Br. at 26-36. Resolving the dispute over diagnosis is not required for this opinion but a finding in Ms. Dotson's favor would be required to award her compensation.

V. Conclusion

Regardless of the label put on B.M.'s condition, the medical records show that his December 2014 illness has caused him a tremendous amount of trouble. Ms. Dotson and B.M. are entitled to sympathy for their suffering. However, special masters are required to resolve cases based upon evidence, not emotion. In this case, the evidence does not preponderate in Ms. Dotson's favor.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master